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QS

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/392,500 09/09/99 TAYLOR

R 9426-019

020583
PENNIE AND EDMONDS
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NEW YORK NY 10036-2711

HM12/1024

EXAMINER

CANELLA, K

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

15
10/24/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/392,500

Applicant(s)

Taylor et al

Examiner

Kar n Canella

Art Unit

1642



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 months MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-34, 48-53, 55, 56, and 58-61 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-34, 48-53, 55, 56, and 58-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 12 20) ☐ Other: _____

Art Unit: 1642

Response to Amendment

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
2. Claims 43-45, 54 and 57 have been canceled. Claims 58-61 have been added. Claims 20-24, 26, 27, 29-34, 48-53, 55 and 56 have been amended. Claims 20-34, and 48-53, 55, 56 and 58-61 are pending and under consideration.
3. Claims 58-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 58-61 fail to relate the administration of one or more antibodies known to bind to improperly glycosylated cancer cells in a subject to the detection of cancer in a subject as only the detection of the anti-C3bi antibody via a detectable label is related to the presence of cancer.
4. Claims 20-34, 48-53, 55 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kinders et al (US 6,221,621) in view of Perlman et al (Journal of Experimental Medicine, 1981, Vol. 153, pp. 1592-1603) and Michael et al (FASEB, 1993, Vol. 7, p A375). The instant claims are drawn in part to a method of detecting cancer comprising the administration of a labeled anti-C3bi antibody. Kinders et al teach a method of detecting cancer comprising the detection of C3. Kinders et al do not teach a method of detecting cancer comprising the detection of C3bi. Perlman et al teach that C3bi constituted the largest C3 fragment that was deposited on target cells (page 1595, lines 6-7). Michael et al teach that malignant epithelial cells synthesize C3bi. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to substitute the detection of C3bi with the detection of C3 in a method of detecting cancer. One of ordinary skill in the art

Art Unit: 1642

would have been motivated to do so with a reasonable expectation of success by the teachings of Perlman et al and Michael et al on the prevalence of C3bi associated with malignant target cells.

5. All other rejections and objections as stated in Paper No. 11 are withdrawn.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.
Patent Examiner, Group 1642
October 22, 2001


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SUPERVISORY PATENT EXAMINER
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